

**K113381 MYSONO U6 DIAGNOSTIC ULTRASOUND SYSTEM**Dec 29, 2011  
43 days to decisionK113381 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k113381/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 16, 2011
Decision date	Dec 29, 2011
Days to decision	43 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Samsung Medison Co., Ltd.</b>
Location	Seoul, KR
Contact	KYEONG-MI PARK
Website	<a href="http://www.medison.com/">http://www.medison.com/</a>
510(k) history	72 submissions · 72 cleared · 2011-2026

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026